



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,372	10/26/2006	Minoru Kohara	KUZ0031US.NP	8112
26259	7590	07/28/2009	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			SASTRI, SATYA B	
			ART UNIT	PAPER NUMBER
			1796	
			NOTIFICATION DATE	DELIVERY MODE
			07/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 10/584,372	Applicant(s) KOHARA, MINORU	
	Examiner SATYA B. SASTRI	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to amendment filed on 4/17/09. Claims 1-5, 7-11 are now pending in the application.

2. As noted in paragraph 2 of the prior office action, applicants were requested to file a certified copy of the priority application, JP2004-002491, as required by 35 U.S.C. 119(b). While the remarks section indicates providing a certified copy of JP2004-002491 concurrently with the amendment filed on 4/17/09, no such submission has been made to date.

Previously Cited Statutes

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The inclusion in claim language of a term within parentheses renders the claim indefinite because it is unclear whether the term within parenthesis is part of the claimed invention or is an optional element. Claim may be amended to recite the limitations within parenthesis as part of the claimed invention.

5. Claims 1-5, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukochi et al. (WO 03/062342) in view of Hori et al. (US 6,146,656).

At the outset, it is noted that WO 03/062342 is used for date purposes where as US 7,034,083 B2 is used as it's equivalent in the rejection set forth below.

Prior art to Yasukochi et al. discloses pressure sensitive adhesive and patch employing the same. The disclosed adhesive contains a polymer which comprises one or more kinds of acrylic or methacrylic monomer units, at least one kind of units having hydroxy group, and which has been crosslinked by boron compound (ab.).

Specific examples of hydroxy group-containing acrylic monomer units include 2-hydroxyethyl (meth)acrylate (col. 2-3, bridging paragraph). The acrylic monomers may include (meth)acrylate esters and other copolymerizable monomers of which 2-ethylhexyl and vinyl pyrrolidone. A particularly preferred copolymer is that of 2-ethylhexyl acrylate, 2-ethylhydroxy acrylate and N-vinyl pyrrolidone (col. 3, lines 15-54).

With regard to the crosslinking agent, the prior art discloses boric acid and derivatives thereof, such as borates and boric esters. With regard to the borate, chemically acceptable inorganic and organic salts such as sodium and ammonium borate, and esters such as methyl borate, ethyl borate, propyl borate, butyl borate etc. are disclosed. Of

Art Unit: 1796

these, boric acid is particularly preferred (col. 3-4, bridging paragraph). The boron-containing compound may be present in amounts of 0.01 to 20 wt.% based on the wt. of the adhesive composition (col. 4, lines 10-17). It is noted that the presently claimed pseudo-crosslinking compound of claim 7 reads on borates and boric acid.

The prior art fails to disclose (1) an adhesive layer having the presently claimed ratio of plasticizer to crosslinking compound, (2) an acrylic copolymer having the presently claimed amount of 2-hydroxyethyl (meth)acrylate content and (3) presently claimed properties of the adhesive layer.

Secondary reference to Hori et al. is in an analogous field of art concerning percutaneous absorption preparation. Hori et al. disclose that the use of an organic liquid ingredient, analogous to Yasukochi et al., in amounts of 25 to 200 parts by wt. of the pressure sensitive adhesive. T disclosure teaches that the organic liquid plasticizes the adhesive layer and given that amounts lower than 25 parts of the liquid is not advantageous in imparting a soft feeling to the skin and greater amounts than 200 parts lowers the cohesive force and consequently, skin irritation upon peeling (col. 5, lines 23-50). Thus, it would have been obvious to one of ordinary skill in the art to include an organic liquid ingredient to plasticize the adhesive layer, in any amount within the disclosed range including in amounts that falls within the presently recited range of claim 1.

With regard to the amount of hydroxyl group-containing monomer, Hori et al. disclose, the polymer includes as an essential ingredient, 1-50% by wt. and preferably, 3-20% by wt. of at least one monomer selected from carboxyl-containing monomer and a hydroxyl group-containing monomer, and if necessary, not greater than 40% by wt. of N-

Art Unit: 1796

vinyl pyrrolidone (col. 4, lines 30-45). Furthermore, specific examples of disclosed polymers as well as working examples include a 2-ethylhexyl acrylate as a comonomer (col. 4, lines 47-56). Given the teaching that 1-50% by wt. of hydroxyl-containing monomer is advantageous from the viewpoint of adhesion properties such as adhesion and cohesion or releasability (col. 4, lines 30-22), it would have been obvious to one of ordinary skill in the art to include a hydroxy group- containing monomer from a small genus comprising two species, i.e. acid-containing monomer and hydroxyl-containing monomer, in amounts of 1-50% by wt. of the copolymer in the adhesive compositions of Yasukochi et al.

While the prior art is silent with regard to the limitations concerning shearing strain migration length recited in instant claim 1, it is the examiner's position that modified Yasukochi et al. adhesive composition must necessarily possess this property because the modified Yasukochi et al. meet the compositional requirements as recited in claim 1. As such, Yasukochi et al. disclose that hydroxy functional groups are less reactive compared to other functional groups, i.e. carboxy and amino groups and crosslinking of hydroxy group with borate may be accomplished under mild conditions (col. 1, lines 36-65). Thus, it is the examiner's position that the borate compound functions as a pseudo-crosslinking compound and crosslink via hydrogen bonding and/or vander Waals force with the polar hydroxyl groups in the acrylic copolymer as presently claimed in claim 11. Thus, the presently recited properties in terms of shearing strain migration must necessarily be intrinsic to the modified Yasukochi et al. compositions, absent evidence to the contrary.

With regard to claims 4 and 5, working examples 2 and 5 of Hori et al. disclose an acrylic copolymer comprising 2-ethylhexyl acrylate, acrylic acid and N-vinyl pyrrolidone (a 75:3:22 wt. ratio). It would have been within the level of ordinary skill in the art to replace acrylic acid in the copolymer with functionally equivalent amount of hydroxyethyl (meth)acrylate given the teaching on functional equivalence of carboxyl-containing monomers and hydroxyl-containing monomers (col. 4, lines 38-45).

With regard to claim 8, Yasukochi et al. teach that the adhesive compositions may be applied to a support layer and further adhered to a release layer when used in patches (col. 7, lines 10-35).

With regard to claims 9 and 10, Yasukochi et al. teach optional use of liquid component that is compatible with the polymer and acts as an absorption promoting agent, solubilizing agent, plasticizer etc. (col. 4, lines 18-35) and a wide choice of drugs (col. 4, lines 43-67, col. 5-6).

Response to Arguments

6. All objections to the specification and claims have been withdrawn either in view of the amendment or because applicant's arguments are found persuasive. Furthermore, applicant's arguments with regard to Kamiyama and Holguin et al. references have been found persuasive and therefore, all previous prior art rejections have been withdrawn. New grounds of rejection are presented herein.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satya Sastri at (571) 272 1112. The examiner can be reached on Mondays, Thursdays and Fridays, 7AM-5.30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. David Wu can be reached on 571-272-1114.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satya B Sastri/

Examiner, Art Unit 1796